

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

45-05

7/7/05

VERIFICATION OF ACTIVITIES RELATED TO AN ESTABLISHMENT'S CONTROLS FOR THE USE OF INGREDIENTS OF PUBLIC HEALTH CONCERN

I. PURPOSE

This notice provides inspection program personnel with instructions for verifying that establishments have the appropriate process controls in place for ingredients that are public health concerns because they can trigger food sensitivities (such as food allergies and intolerances). This notice is necessary because of the sustained number of recalls associated with adulterated and misbranded meat and poultry products because of the undeclared presence of ingredients that are capable of causing adverse reactions.

II. BACKGROUND

A. The recalls associated with products that contain undeclared ingredients which are associated with adverse reactions reflect a potential health hazard situation. The occurrence of a recall indicates that the HACCP system in the affected establishments has not been as effective as necessary to protect public health. Awareness by FSIS inspection program personnel of the consequences of undeclared ingredients is critical for protecting public health.

B. Inspection program personnel need to be aware that certain food ingredients have been associated with adverse reactions, such as food allergies and intolerances. Eight categories of foods are often associated with food allergies which are adverse immunological reactions in sensitive individuals due to the protein in these foods. They are wheat, Crustacea (e.g., shrimp, crab, lobster), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), and soybeans.

Other potential causes of adverse reactions in sensitive individuals are ingredients, such as, monosodium glutamate (MSG), sulfites, lactose, and Yellow 5 (tartrazine). The adverse reactions to these substances are due to the ingredient itself or its chemical composition.

DISTRIBUTION: Inspection
Offices;T/A Inspectors;Plant Mgt;T/A
Plant Mgt;ABB;PRD;Import Offices

NOTICE EXPIRES: 8/1/06

OPI: OPPED

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. Inspection program personnel should review the establishment's flow chart and hazard analysis to verify that:

1. the flow chart and hazard analysis identify which products may contain ingredients that cause adverse reactions, and
2. the establishment has adequately incorporated into its food safety systems (i.e., HACCP plans, Sanitation SOPs, or prerequisite programs) procedures for properly formulating products, applying the appropriate label, and accurately labeling the product to fully disclose the use of all ingredients, particularly those that may cause adverse reactions.

NOTE: If establishments have addressed the control of ingredients in a prerequisite program to prevent a food safety hazard from being likely to occur, inspection program personnel are to verify that an Enforcement, Investigations and Analysis Officer (EIAO) has conducted a comprehensive food safety assessment at the establishment. If an EIAO has not had an opportunity to do so, inspection program personnel are to contact the District Office and inform it of the situation.

B. Inspection program personnel are to take the appropriate enforcement action as set out in FSIS Directive 5000.1, Revision 1 and issue a non-compliance record under the appropriate 03 ISP code when the establishment:

1. has not addressed the use and control of ingredients that may cause adverse reactions in its hazard analysis,
2. has not followed its procedures as set out in its food safety systems, or
3. has not properly disclosed on the product label that the product's formulation includes the use of an ingredient that is known to cause an adverse reaction.

Any questions should be referred to the Technical Service Center at 1-800-233-3935.

Philip S. Derfler /s/

Deputy Administrator
Office of Policy, Program, and Employee Development